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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/600,802	06/19/2003	Jennie P. Mather	415072002500	9712

25226 7590 10/09/2007

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EXAMINER	
DAVIS, MINH TAM B	

ART UNIT	PAPER NUMBER
1642	

MAIL DATE	DELIVERY MODE
10/09/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/600,802	MATHER ET AL.	
	Examiner	Art Unit	
	MINH-TAM DAVIS	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 July 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) *3-11 and 16-24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2 and 12-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/3/03;6/7/05;6/11/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's election without traverse of Group A, claims 1-2, 12-15, species lung cancer, and the hybridoma cell line having ATCC No: PTA-4217 in paper of 07/20/07 is acknowledged.

After review and reconsideration, the species hybridoma cell lines having ATCC Nos: PTA-4218, PTA-4244, and PTA-4245 are rejoined with the hybridoma cell line having ATCC No: PTA-4217, in view that there is no art for the claimed hybridoma cell line.

Accordingly, group A, claims 1-2, 12-15, species lung cancer are examined in the instant application.

The embodiment of claims 1-2, 12-15 as being drawn to species cancers other than lung cancer, as recited in claim 2, have been withdrawn from consideration as being drawn to non-elected species.

Claim Rejections - 35 USC § 112, First Paragraph, Deposit Requirement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 15 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 15 is rejected under the deposit rule requirement, and adeposit for patent purposes of the hybridoma Accession Nos: PTA-4217, PTA-4218, PTA-4244, and PTA-4245 is required to enable the invention of claim 15, because it is not clear that the hybridoma Accession Nos: PTA-4217, PTA-4218, PTA-4244, and PTA-4245 are known and publicly available or can be reproducibly isolated without undue experimentation. Without a publicly available deposit of the hybridoma Accession Nos: PTA-4217, PTA-4218, PTA-4244, and PTA-4245, one of ordinary skill in the art could not be assured of the ability to practice the invention as claimed. Exact replication of the hybridoma Accession Nos: PTA-4217, PTA-4218, PTA-4244, and PTA-4245, which produce chemically and functionally distinct antibodies is an unpredictable event. For example, very different V_H chains (about 50% homologous) can combine with the same V_K chain to produce antibody-binding sites with nearly the same size, shape, antigen specificity, and affinity. A similar phenomenon can also occur when different V_H sequences combine with different V_K sequence to produce antibodies with very similar properties. The results indicate that divergent variable region sequences, both in and out of the complementary determining regions, can be folded to form similar binding contours, which result in similar immunochemical characteristics (William E. Paul, ed., 3rd ed. 1993, Fundamental Immunology, p. 242). The claimed hybridoma Accession Nos: PTA-4217, PTA-4218, PTA-4244, and PTA-4245 are distinct and having unique properties; and one of ordinary skill in the art would be forced into undue experimentation in order to make the claimed hybridoma Accession Nos: PTA-4217, PTA-4218, PTA-4244, and PTA-4245, in view of the lack of exemplary materials and in view of the unpredictability associated with obtaining the exact species repeatedly. A deposit of the

hybridoma Accession Nos: PTA-4217, PTA-4218, PTA-4244, and PTA-4245 would satisfy the requirements of 35 USC 112 first paragraph in this case. See CFR 1.801-CFR 1.809.

Further, Applicant is required to submit a statement, reciting that all restrictions upon public access to the deposits will be irrevocably removed upon the granting of a patent on this application, and that the deposit will be replaced if viable samples cannot be dispensed by the depository. It is noted that "even a deposit made under the Budapest Treaty and referenced in a United States or foreign patent document would not necessarily meet the test for known and readily available unless the deposit was made under conditions that are consistent with those specified in these rules, including the provision that requires, with one possible exception (37 CFR 1.808(b)), that all restrictions on the accessibility be irrevocably removed by the applicant upon the granting of the patent. Ex parte Hildebrand, 15 USPQ2d 1662 (Bd. Pat. App. & Int. 1990)". Further, a product could be commercially available but only at a price that effectively eliminates accessibility to those desiring to obtain a sample. See also the final rule entitled "Deposit of Biological Materials for Patent Purposes," 54 FR 34864, 34875 (August 22, 1989). Applicant's attention is directed to 37 CFR 1.801-1.809 for further information concerning deposit practice.

Sequence Rule

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 C.F.R. 1.821-25 for the reasons set forth below:

The specification recites sequences without being accompanied by sequence identification numbers, for example, the sequences on tables 1-2 on page 66.

Claim Rejections - 35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-2, 12-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1. Claims 1-2, 12-14 are indefinite for the use the use of the language "RAAG10" in claims 1, 13, as the sole means of identifying the claimed antigen. The use of laboratory designation only to identify a particular antigen renders the claim indefinite because different laboratories may use the same laboratory designations to define completely distinct antigens. Amendment of the claims to incorporate for example, a sequence identification number, to include physical and/or functional characteristics of "RAAG10" which unambiguously define "RAAG10", is suggested.

2. Claim 15 is indefinite, because it is not clear what constitutes "a progeny" of a cell line.

Claim Rejections - 35 USC § 112, First Paragraph, Written Description

Claims 1-2, 12-14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant

art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification discloses that "RAAG10" and B7-H3L refer to a novel glycosylated protein, having a molecular weight of about 100 kD, to which the claimed antibodies bind (p.13, para 0040, p.53, para 0151). The specification suggests that RAAG10 to which the claimed antibody bind may be a duplicate of the extracellular domain of the known polypeptide B7 homolog 3 (B7H3), but is a much larger sequence (p.58, para 0165, bridging p.59, p.60, para 0169). The **exact** RAAG10 **amino acid sequence however is not known**, in view that the initiation AUG codon could not be identified (p.59, para 0166). The specification discloses the amino acid fragments of the B7H3 sequence known in the art, to which the claimed three monoclonal antibodies cross-react and bind (Table 3 on page 67, p.62, para 0175, p.60, para 0169). It is noted that the sequences cited in table 1 on page 66 are the amino acid sequence of the B7H3 sequence known in the art, and its fragments.

The art does not disclose structure of the genus of RAAG10 variants.

In view of the disclosure in the specification, RAAG10, without being accompanied by a sequence identification number, encompasses a **genus** of glycosylated proteins, having a molecular weight of about 100 kD. The disclosed monoclonal antibodies do not define the claimed RAAG10, because the epitopes of the disclosed monoclonal antibodies are only fragments of a known polypeptide, which shares some epitopes with the whole length protein RAAG10, the structure of which whole length RAAG10 protein is not disclosed. It is noted that an epitope of a monoclonal antibody could be as small as three or four amino acids.

Although drawn to DNA arts, the findings in University of California v. Eli Lilly and Co., 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997) and Enzo Biochem, Inc. V. Gen-Probe Inc. are relevant to the instant claims. The Federal Circuit addressed the application of the written description requirement to DNA-related inventions in University of California v. Eli Lilly and Co., 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997). The court stated that "[a] written description of an invention involving a chemical genus, like a description of a chemical species, requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials." Id. At 1567, 43 USPQ2d at 1405. The court also stated that

> a generic statement such as "vertebrate insulin cDNA" or "mammalian insulin cDNA" without more, is not an adequate written description of the genus because it does not distinguish the genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is. Id. At 1568, 43 USPQ2d at 1406. The court concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material." Id.

Finally, the court addressed the manner by which a genus of cDNAs might be described. "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus." Id.

The Federal Circuit has recently clarified that a DNA molecule can be adequately described without disclosing its complete structure. See Enzo Biochem, Inc. V. Gen-Probe Inc., 296 F.3d 1316, 63 USPQ2d 1609 (Fed. Cir. 2002). The Enzo court adopted the standard that □the written description requirement can be met by "show[ing] that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics ....i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics." Id. At 1324, 63 USPQ2d at 1613 (emphasis omitted, bracketed material in original).

The inventions at issue in Lilly and Enzo were DNA constructs per se, the holdings of those cases are also applicable to claims such as those at issue here.

In this case, the specification does not describe RAAG10 in a manner that satisfies either the standards as shown in the example of Lilly or Enzo. The specification does not provide sufficient structure or common structure to support the broad breath of the claimed genus. Nor is there any functional characteristics coupled with a known or disclosed correlation between structure and function. Although the specification discloses structure of the amino acid fragments from a known polypeptide B7-H3, that the claimed antibodies cross-react and bind to, this does not provide a description of RAAG10, that would satisfy the standard as shown in the example of Enzo.

The specification also fails to describe RAAG10, by the standards shown in the example in Lilly. The specification describes only amino acid fragments to which the claimed antibodies bind. Therefore, it necessarily fails to describe a "representative number" of such species. In

addition, the specification also does not describe "structural features common to the members of the genus, which features constitute a substantial portion of the genus."

Further, the following teaching of the court as set out in Noelle also clearly applies to the instant claimed invention. The court teaches as follows: "Noelle did not provide sufficient support for the claims to the human CD40CR antibody in his '480 application because Noelle failed to disclose the structural elements of human CD40CR antibody or antigen in his earlier '799 application. Noelle argues that because antibodies are defined by their binding affinity to antigens, not their physical structure, he sufficiently described human CD40CR antibody by stating that it binds to human CD40CR antigen. Noelle cites Enzo Biochem II for this proposition. This argument fails, however, because Noelle did not sufficiently describe the human CD40CR antigen at the time of the filing of the '799 patent application. In fact, Noelle only described the mouse antigen when he claimed the mouse, human, and genus forms of CD40CR antibodies by citing to the ATCC number of the hybridoma secreting the mouse CD40CR antibody. If Noelle had sufficiently described the human form of CD40CR antigen, he could have claimed its antibody by simply stating its binding affinity for the "fully characterized" antigen. Noelle did not describe human CD40CR antigen. Therefore, Noelle attempted to define an unknown by its binding affinity to another unknown. As a result, Noelle's claims to human forms of CD40CR antibody found in his '480 application cannot gain the benefit of the earlier filing date of his '799 patent application. Moreover, Noelle cannot claim the genus form of CD40CR antibody by simply describing mouse CD40CR antigen". *Randolph J. Noelle v Seth Lederman, Leonard Chess and Michael J. Yellin* (CAFC, 02-1187, 1/20/2004).

In the instant application, the specification only discloses fragments of another

polypeptide, B7-H3, to which the claimed antibody binds. The instant application does not however fully describe the structure of the claimed RAAG10, having a molecular weight of about 100 kD.

Since the instant application does not fully describe the genus of antigen to which the claimed antibody binds, the instant application cannot claim the genus form of antibody by simply describing the antigen consisting of a fragment of a known polypeptide, B7-H3. Thus the specification fails to describe the claimed antibody, by the test set out in the example of Noelle.

The specification does not provide an adequate written description of RAAG10, that is required to practice the claimed invention. Thus, the specification does not meet the 112, first paragraph written description requirement, and one of skill in the art would reasonably conclude that Applicant did not have possession of the claimed RAAG10, at the time the invention was made.

Claim Rejections - 35 USC § 112, First Paragraph, Enablement

Claims 1-2, 12-15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

To comply with the enablement requirement of 35 U.S.C. § 112, first paragraph, the specification must enable one skilled in the art to make and use the claimed invention without undue experimentation. The claims are evaluated for enablement based on the Wands analysis. Many of the factors regarding undue experimentation have been summarized in *In re Wands*,

858 F.2d 731,8 USPQ2d 1400 (Fed.Circ.1988) as follows: (1) the nature of the invention, (2) the state of the prior art, (3) the predictability or lack thereof in the art, (4) the amount of direction or guidance present, (5) the presence or absence of working examples, (6) the quantity of experimentation necessary, (7) the relative skill of those in the art, and (8) the breadth of the claims.

The disclosure in the specification has been set forth above. The specification further discloses binding data of the claimed monoclonal antibodies to lung cancer tissue (table 7 on page 72), and normal lung tissue (table 8 on page 73). However, the data do not show a difference between the intensity of the detetected monoclonal antibody PA20 (PTA-4244, p.52, para 0149)) on lung cancer tissue (Table 7, on page 72, column before last) as compared to the control normal lung tissue (Table 8, on page 73, column before last). The specification contemplates treating cancer, using the claimed antibody (p.8, para 0027, bridging p.59). The specification, however, does not have any data or concrete evidence that lung cancer could be successfully treated using the claimed antibody.

RAAG10, without being accompanied by a sequence identification number, as claimed in claims 1-2, 12-14, encompasses a **genus** of glycosylated proteins, having a molecular weight of about 100 kD, supra. Further, the ability of the claimed antibody "to **deliver a therapeutic agent** into a cancer cell", as claimed in claims 1, 13, encompasses the ability to treat cancer using by the claimed antibody, as contemplated in the specification. Further, a "pharmaceutical composition", as claimed in claims 12-14 encompasses an in vivo use, such as treating cancer, as contemplated in the specification.

1. Claims 1-2, 12-14 are rejected under 112, first paragraph for lack of enablement for an antibody to **RAAG10**, that could be used for **treating cancer**.

One would not know how to make the claimed genus of RAAG10 polypeptides, having a molecular weight of about 100 kD, to which the claimed antibody binds, because the structure of such polypeptides is not disclosed nor predictable. The disclosed monoclonal antibodies do not define the claimed RAAG10, because the epitopes of the disclosed monoclonal antibodies are only fragments of a known polypeptide, which shares some epitopes with the whole length protein RAAG10. The structure of which whole length RAAG10 protein is not disclosed, nor predictable, supra. It is noted that an epitope of a monoclonal antibody could be as small as three or four amino acids.

Further, one cannot predict that the claimed antibody could be successfully used for treating cancer, in view that cancer treatment is highly unpredictable. White et al, 2001 (Ann Rev Med, 52: 125-145), teach that for a successful immunotherapy, besides the specificity of the antigen, other following properties of the antigen should also be considered: The antigen should be present on all or near all of the malignant cells to allow effective targeting and to prevent a subpopulation of antigen-negative cells from proliferating. Further, antibodies have been developed against a broad spectrum of antigens, and whether the antigens shed, modulate or internalize influence the effectiveness of the administered antibody (p.126, second paragraph). Moreover, antigen internalization or downregulation can cause repeat dosing to be unsuccessful due to the disappearance of the antibody target (p.126, paragraph before last). Furthermore, cancer tolerance is a well known phenomenon. Boon, 1992 (Adv Can Res, 58:177-210) teaches that for active immunization in human patients we have to stimulate immune defenses of

organisms that have often carried a large tumor burden. Establishment of immune tolerance may therefore have occurred and it may prevent immunization and several lines of evidence suggest that large tumor burdens can tolerize or at least depress the capability to respond against the tumor (p. 206, para 2). In addition, Boon teaches that even if activated CTLs are significantly increased, the therapeutic success remains unpredictable due to inconsistencies in antigen expression or presentation by tumor cells, such as loss of tumor antigen (p.198, first paragraph). Kirkin et al, 1998, APMIS, 106 : 665-679, teach that although several peptides of melanoma associated antigens have been identified as recognized by CTL in vitro, and in particular peptides from MAGE-A1 and MAGE-A3 have been tested for their ability to induce anti-melanoma immune response in vivo, so far only one of the peptides, peptide EVDPIGHLY of MAGE-A3, has limited anti-tumor activity, indicating their low immunogenicity (p.666, second column, second paragraph, last 6 lines). Smith RT, 1994 (Clin Immunol, 41(4): 841-849), teaches that antigen overload, due to antigen shedding by actively growing tumor, could block specifically either cytotoxic or proliferative responses of tumor specific T cells (p. 847, last paragraph bridging p.848 and p.848). Smith further teaches that many tumors progressively lose MHC representation at the surface of the cell, and the loss of surface Class I MHC could severely limits the possibilities for cytotoxic T cells specific for a tumor specific antigen to find said tumor specfic antigen in the necessary MHC context (p.484). Bodey et al, 2000, Anticancer Res, 20: 2665-2676, confirm the teaching of Boon and Smith, by explaining the reasons for failure of vaccine in human. Bodey et al teach that although general immune activation against the target antigens has been documented in most cases, reduction of tumor load has not been frequently observed in human patients (abstract, second column, p.2673). Bodey et al teach that the failure

of cancer vaccine is due to natural selection of highly aggressive clones in the treated patient, said clones no longer express the cancer specific antigen (abstract, second column, p.2673). Bodey et al teach that these clones of tumor cells survive the immune system, through secretion of immunoinhibitory cytokines, downregulation of MHC, loss of costimulatory molecules, and induction of T cell anergy (p.2673, second column, last paragraph). Thus, in view of the teaching in the art, one cannot predict that the claimed antibody could be used for treating cancer.

2. Claim 15 is also rejected under 112, first paragraph, because one cannot predict that the monoclonal antibody produced by **PTA-4244** cell line could be used for diagnosing or treating lung cancer.

One cannot predict that the monoclonal antibody produced by **PTA-4244** cell line (PA20) could be used for diagnosing or treating lung cancer, because the monoclonal antibody produced by **PTA-4244** cell line could not detect a difference in the level of the targeted RAAG10 between lung cancer tissue and normal lung tissue, as shown in tables 7-8, on pages 72-73, under PA20, respectively. The signal produced by the monoclonal antibody produced by **PTA-4244** cell line is weak or absent in both lung cancer tissue and normal lung tissue. Therefore, one would not know how to use the claimed cell line PTA-4244.

3. Claim 15 is also rejected under 112, first paragraph, because one would not know how to make a progeny of the claimed cell line, such that it would produce an antibody that could be used for diagnosis of a lung cancer.

Since it is not clear what a progeny of the claimed cell lines is, one would not know how to make the claimed progeny, such that it would produce an antibody that could be used for diagnosis of lung cancer.

MPEP 2164.03 teaches that "the amount of guidance or direction needed to enable the invention is inversely related to the amount of knowledge in the state of the art as well as the predictability of the art. In re Fisher, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). The amount of guidance or direction refers to that information in the application, as originally filed, that teaches exactly how to make or use the invention. The more that is known in the prior art about the nature ot the invention, how to make, and how to use the invention, and the more predictable the art is, the less information needs to explicitly stated in the specification. In constrast, if little is known in the prior art about the nature of the invention and the art is unpredictable, the specification would need more detail as how to make and use the invention in order to be enabling."

Given the above unpredictability, and in view of the complex nature of the invention, a lack of sufficient disclosure in the specification, and little is known in the art concerning the claimed invention, it would have been undue experimentation for one of skill in the art to practice the claimed invention, that is commensurate in scope of the claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-2 are rejected under 35 U.S.C. 102(e) as being anticipated by US 6,891,030 (Chen, filed on 07/26/01), as evidenced by Banki et al, 1994, JBC, 269 (4): 2847-51, or Bendayan et al, 1995, J Histochem Cytochem, 43(9): 881-886).

Claim 1. A substantially purified immunoglobulin polypeptide or an antigen binding fragment thereof, that specifically binds to RAAG10, and has at least one or more of the following characteristics:

a. the ability to bind to RAAG10 on a cancer cell;

b. ability to bind to a portion of RAAG10 that is exposed on the surface of a living cell in vitro or in vivo;

c. ability to deliver a therapeutic agent or detectable marker to a cancer cell expressing RAAG10; and

d. ability to deliver a therapeutic agent or detectable marker into a cancer cell expressing RAAG10.

Claim 2. The purified immunoglobulin polypeptide or antigen binding fragment of claim 1, wherein said cancer cell is lung cancer.

The specification discloses that RAAG10 or B7-H3L is a duplicate of the extracellular domains, consisting of two IgG-like domains, of the known B7-H3 protein (p.58, last paragraph, bridging p.59).

Chen teaches antibody to antibodies to B7-H3 polypeptide or fragments thereof (column 17, last paragraph, bridging column 18). Chen et al teach different domains of 316 amino acid B7-H3 polypeptide, which contain a signal peptide, a single extracellular V-like Ig domain, a single C-like Ig domain, a transmembrane region, and a cytoplasmic tail (column 22, lines 18-21).

The antibody to the extracellular domain of B7-H3 polypeptide taught by Chen would bind to the claimed RAAG10, as evidenced by Banki et al, which teach that an antibody against human transaldolase could bind to yeast transaldolase which is about 58% homologous with human transaldolase, i.e. an antibody could cross-react and bind to a polypeptide at least with 58% homology to its antigen (abstract), or by Bendayan et al, which teach that anti-human proinsulin monoclonal antibody to the Arg-Arg dipeptide, although providing very specific binding results, cross-reacts with non-related molecules, i.e., rat, bovine, porcine and human glucagons (abstract).

Although the reference does not explicitly teach that the antibody binds to RAAG10 on a cancer cell, or lung cancer cell, however, the claimed antibody appears to be the same as the prior art antibody, absent a showing of unobvious differences. The office does not have the facilities and resources to provide the factual evidence needed in order to establish that the product of the prior art does not possess the same material, structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is on the applicant to prove that the claimed product is different from those taught by the prior art and to establish patentable differences. See In re Best 562F.2d 1252, 195 USPQ 430 (CCPA 1977) and Ex parte Gray 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int. 1989).

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MINH-TAM DAVIS whose telephone number is 571-272-0830. The examiner can normally be reached on 9:00 AM-5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, SHANON FOLEY can be reached on 571-272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MINH TAM DAVIS
September 10, 2007

/Larry R. Helms/

Supervisory Patent Examiner